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EXAMINER
BERTAGNA, ANGELA MARIE

ART UNIT	PAPER NUMBER
1637	

NOTIFICATION DATE	DELIVERY MODE
02/29/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

dcptopatent@hhlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/552,159	SADARANGANI ET AL.	
	Examiner	Art Unit	
	ANGELA BERTAGNA	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/11/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-25, in the reply filed on December 5, 2007 is acknowledged. Claims 26-57 drawn to a non-elected invention were canceled in the response.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

2. Receipt is acknowledged of a certified copy of the 525198 and 527519 applications filed in New Zealand. If these copies are being filed to obtain the benefits of the foreign filing date under 35 U.S.C. 119(a)-(d), applicant should also file a claim for such priority as required by 35 U.S.C. 119(b). If the application being examined is an original application filed under 35 U.S.C. 111(a) (other than a design application) on or after November 29, 2000, the claim for priority must be presented during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior foreign application. See 37 CFR 1.55(a)(1)(i). If the application being examined has entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the claim for priority must be made during the pendency of the

application and within the time limit set forth in the PCT and Regulations of the PCT. See 37 CFR 1.55(a)(1)(ii). Any claim for priority under 35 U.S.C. 119(a)-(d) or (f) or 365(a) or (b) not presented within the time period set forth in 37 CFR 1.55(a)(1) is considered to have been waived. If a claim for foreign priority is presented after the time period set forth in 37 CFR 1.55(a)(1), the claim may be accepted if the claim properly identifies the prior foreign application and is accompanied by a grantable petition to accept an unintentionally delayed claim for priority. See 37 CFR 1.55(c).

Information Disclosure Statement

3. The information disclosure statement filed on October 11, 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Oath/Declaration

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Claim Interpretation

5. Prior to analysis of the prior art, the claims must be construed. The instant claims are drawn to a DNA analysis system. Sections 2114 and 2115 of the MPEP provide guidance for examination of claims drawn to an apparatus. Section 2114 of the MPEP states, "While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997); see also In re Swinehart, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971); In re Danly, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959); and Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990)."

Section 2114 of the MPEP further states, "A claim containing a 'recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus' if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987)."

Section 2115 of the MPEP indicates that the contents present in an apparatus during its normal operation and the material worked on by the apparatus are not accorded patentable weight during the examination process, stating, "Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. Ex parte Thibault, 164 USPQ 666, 667 (Bd. App. 1969). Furthermore, inclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims. In re Young, 75 F.2d 996, 25 USPQ 69 (CCPA 1935) (as restated in In re Otto, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963))."

In short, sections 2114 and 2115 of the MPEP indicate that the structural features of an apparatus define its patentability rather than the contents of the apparatus, the material worked on or produced by the apparatus, or the manner of operating the apparatus. Therefore, the limitation appearing in claims 1 and 4 reciting a proteinase contained in the extraction unit has not been given patentable weight, because this element does not impart a structural difference in the apparatus. In other words, the recited proteinase is part of the contents present in the apparatus during its normal operation, and therefore, is not relevant to patentability.

Similarly, the phrases “for extracting DNA from a sample to be tested", "for replicating identically a region of interest in DNA strands extracted from the sample", "for purifying the amplified material from the thermal cycler", and "for analyzing the purified sample to obtain genetic information relating to the sample" appearing in claim 4 are intended use recitations that do not further limit the structure of the claimed apparatus. Similar intended use recitations appear in claims 7, 13, 15, 17, 19, 20, 22, and 24. These intended use recitations do not further limit the structural features of the apparatus, and therefore, they have not been accorded patentable weight.

Lastly, the limitations recited in claims 2, 9-11, and 18 describe the manner in which the apparatus is operated rather than defining the structure of the apparatus. As a result, these limitations have not been accorded patentable weight, since they do not further limit the structural features of the claimed apparatus.

Claim Rejections - 35 USC § 112, 2nd paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-25 are indefinite, because independent claims 1 and 4 recite that the DNA analysis system includes a proteinase "as defined". There is no further definition of the metes and bounds of "as defined" in the claims, and therefore, the use of the phrase "as defined" renders the claim scope insolubly unclear. Since all of the claims depend from claim 1 or claim 4, they are also indefinite.

Claims 4-25 are further indefinite, because the terms "extraction stage", "amplification stage", "purification stage", "analysis stage", "separation stage", "detection stage", and "sequencing stage" are used interchangeably to describe apparatus limitations and method steps related to the operation of the apparatus. For example, the "amplification stage", "extraction stage", "purification stage", and "analysis stage" recited in claims 4, 5, 8, and 9 appear to be directed to structural features of the claimed DNA analysis system. However, claim 6 recites that the system of claim 4 further includes "a sequencing stage preceding the analysis stage". This recitation appears to be directed to a sequencing method step conducted when operating apparatus prior to an analysis method step. Similar recitations appear in claims 7, 10, 11, 16, 18, and 24. These recitations in claims 6, 7, 10, 11, 16, 18, and 24 cause the meaning of the different stages recited in claims 4, 5, 8, and 9 to be vague and indefinite, because it is not clear whether

the stages recited in the claims refer to method steps conducted during normal operation of the apparatus or to structural features of the apparatus. Since limitations related to method steps conducted when using the apparatus that do not serve to limit the structure of the apparatus do are not accorded patentable weight (see section 5 above), this uncertainty regarding the intended meaning of the various "stages" recited in the claims causes the scope of the claims to be completely unclear. As a result, claim 4 and those claims dependent therefrom (claims 5-25) are indefinite.

Claim 18 is further indefinite, because it recites the limitation "the microcontroller" in line 2. There is insufficient antecedent basis for this limitation in the claim. There is sufficient antecedent basis for "the controller" (see claim 16).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-12, 16-19, 24, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Muir et al. (US 6,251,660 B1; cited previously).

These claims are drawn to a DNA analysis system comprising an extraction stage, an amplification stage, a purification stage, and an analysis stage.

Regarding claims 1 and 4-7, Muir teaches a DNA analysis system comprising:

(a) a thermal cycler operable as an extraction stage for extracting DNA, an amplification stage for amplifying DNA, and a sequencing stage (see Figure 5 and column 19, line 24 - column 20, line 21, where compartment D meets the claimed limitations; see column 8, lines 14-36 for further description of the thermal cycler; see also Figure 14 and column 28, line 33 - column 30, line 47, especially column 30, lines 16-47)

(b) a purification stage (see Figure 5 and column 20, lines 22-30, where compartment E meets this limitation; see also Figure 14 and column 30, line 48 - column 31, line 19)

(c) an analysis stage comprising a separation stage and a detection stage (see Figure 5 and column 20, line 31 – column 21, line 9).

As noted above, the limitation in claims 1 and 4 requiring the presence of a proteinase in the apparatus has not been accorded patentable weight since the protease is part of contents present during the normal operation of the apparatus. It is noted, however, that Muir teaches that the apparatus includes a proteinase in the extraction stage (see column 7, lines 36-47).

Also, as discussed above, the limitations recited in claims 2 and 9-11 have not been accorded patentable weight since they describe how the apparatus is used rather than limiting its structure.

Regarding claims 3, 24, and 25, Muir teaches that the apparatus further includes an attached fluorimeter and light source (see column 20, line 59 – column 42, column 26, lines 44-52, and column 27, lines 1-6, and column 34, lines 14-22). The fluorimeter constitutes a means for monitoring the analysis stage and inherently contains a computer having a display.

Regarding claim 8, Muir teaches that the purification stage incorporates a size filtration matrix comprising gel filtration media incorporating a filtering resin that allows the passage of

larger DNA molecules before smaller fragments or other contaminants (see column 8, lines 37-column 9, line 2 and column 9, line 47 - column 10, line 7).

Regarding claim 12, Muir teaches that the separation device is an electrophoresis device (see Figure 14 and column 28, line 64 - column 30, line 15; see also column 31, lines 25-51).

Regarding claims 16-18, Muir teaches that the thermal cycler includes a controller that controls the various stages of sample preparation and a heating mechanism controlled by a microcontroller (column 8, lines 14-36 and column 30, lines 16-33).

Regarding claim 19, Muir teaches that the system includes a dispensing device for depositing material to be analyzed in the thermal cycler (see column 20, lines 7-21 and column 29, line 20 – column 30, line 47).

9. Claims 1-18, 24, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Woolley et al. (Analytical Chemistry (1996) 68(23): 4081-4086; newly cited).

These claims are drawn to a DNA analysis system comprising an extraction stage, an amplification stage, a purification stage, and an analysis stage.

Regarding claims 1 and 4-7, Woolley teaches a DNA analysis system comprising:

(a) a thermal cycler operable as an extraction stage for extracting DNA, an amplification stage for amplifying DNA, and a sequencing stage (see Figure 1 and pages 4082-4083, where the PCR device meets the claimed limitations)

(b) a purification stage (see Figure 1 and pages 4082-4083, where the capillary electrophoresis device is the purification stage)

(c) an analysis stage comprising a separation stage and a detection stage (see Figure 1 and pages 4082-4083, where the capillary electrophoresis device coupled to a laser-excited confocal detection apparatus meets the claimed limitations).

As noted in section 5, the limitation in claims 1 and 4 requiring the presence of a proteinase in the apparatus has not been accorded patentable weight since the protease is part of contents present during the normal operation of the apparatus.

Also, as discussed above, the limitations recited in claims 2 and 9-11 have not been accorded patentable weight since they describe how the apparatus is used rather than limiting its structure.

Regarding claim 3, Woolley teaches that the apparatus further includes an attached fluorimeter and light source (see Figure 1 and pages 4083-4084, where the laser-excited confocal detection apparatus contains these elements).

Regarding claim 8, Woolley teaches that the purification stage incorporates a size filtration matrix comprising gel filtration media incorporating a filtering resin that allows the passage of larger DNA molecules before smaller fragments or other contaminants (page 4083).

Regarding claims 12-15, Woolley teaches that the separation device is a capillary electrophoresis device that includes a detector that comprises a laser device and a reader (see Figure 1 and pages 4083-4084).

Regarding claims 16-18, Woolley teaches that the thermal cycler includes a controller that controls the various stages of sample preparation and a heating mechanism controlled by a microcontroller (pages 4082-4084).

Regarding claims 24 and 25, Woolley teaches that the apparatus contains a means for monitoring the analysis stage which includes a computer having a display on which data obtained from using the apparatus are displayed (see page 4083, column 2 - page 4084, column 1 and Figures 3-5).

10. Claims 1-7, 16, 17, and 19-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Belgrader et al. (Laboratory Research and Automation (1997) 9: 3-7; newly cited) as evidenced by the ABI Prism 310 Genetic Analyzer User's Manual (1998).

These claims are drawn to a DNA analysis system comprising an extraction stage, an amplification stage, a purification stage, and an analysis stage.

Regarding claims 1 and 4-7, Belgrader teaches a DNA analysis system comprising:

(a) a thermal cycler operable as an extraction stage for extracting DNA, an amplification stage for amplifying DNA, and a sequencing stage (see Figure 1 and pages 4-5, where the thermal cyclers meet these limitations)

(b) a purification stage (see page 4, where the ABI Prism 310 Genetic Analyzer is taught)

(c) an analysis stage comprising a separation stage and a detection stage (see page 4, where the ABI Prism 310 Genetic Analyzer and the associated computer are an analysis stage comprising a separation and detection stage).

As noted in section 5, the limitation in claims 1 and 4 requiring the presence of a proteinase in the apparatus has not been accorded patentable weight since the protease is part of contents present during the normal operation of the apparatus.

Also, as discussed above, the limitations recited in claim 2 have not been accorded patentable weight since they describe how the apparatus is used rather than limiting its structure.

Regarding claim 3, Belgrader teaches that the apparatus further includes an attached fluorimeter and light source (see page 4 and Figure 2, where the ABI Prism 310 Genetic Analyzer contains these elements). See also, pages 23 and 33-37 of the ABI Prism 310 Genetic Analyzer User Manual, which teach that the apparatus contains a fluorimeter and attached light source.

Regarding claims 16 and 17, Belgrader teaches that the thermal cycler includes a controller that controls the various stages of sample preparation and a heating mechanism (see pages 4-5).

Regarding claim 19, Belgrader teaches that the system includes a dispensing device for depositing the material to be analyzed into the thermal cycler (see page 4).

Regarding claim 20, Belgrader teaches that the thermal cycler includes a holder for holding replacement tips for the dispensing device (see Figure 1 and page 4, where the microplate covered with a lid containing holes for the tips to pass through meets the claimed limitation).

Regarding claim 21, Belgrader teaches that the holder is arranged on the thermal cycler adjacent to the heating mechanism and within reach of the movements of the dispensing device (see Figure 1 and pages 4-5).

Regarding claim 22, Belgrader teaches that the holder includes reservoirs for various solutions adjacent to the replacement tips (see Figure 1 and pages 4-5, where the wells in the microplate are reservoirs).

Regarding claim 23, when the holder (*i.e.* the microplate) is inserted into the capillary electrophoresis device as taught by Belgrader (see pages 4-5), the purification stage is mounted on the holder as required by the claim.

Regarding claims 24 and 25, Belgrader teaches that the apparatus contains a means for monitoring the analysis stage which includes a computer having a display on which data obtained from using the apparatus are displayed (see Figure 1 and pages 4-5).

Conclusion

11. No claims are currently allowable.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references are made of record as references of interest: (1) Leushner et al. (US 5,830,657), (2) Swerdlow et al. (US 5,935,522), (3) Gold et al. (US 2002/0064780 A1), (4) Heimberg et al. (US 6,656,724), (5) Paschetto et al. (US 2002/0108857 A1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANGELA BERTAGNA whose telephone number is (571)272-8291. The examiner can normally be reached on M-F, 7:30 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amb /Cynthia B. Wilder, Ph.D./
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